

August 20, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

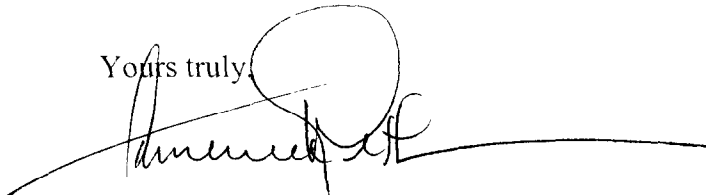
RE: Definition of Primary Mode of a Combination Product [Docket No. 2004N-0194, 69  
Federal Register 25527 (May 7, 2004)]

Dear Sir or Madam:

American Medical Systems Inc. (AMS) appreciates the opportunity to provide comments  
in response to the May 7, 2004 Federal Register Notice regarding the Mode of Action as  
pertains to Combination Products.

AMS has read, and supports AdvaMed's comments of August 20, 2004 regarding the  
definition of Primary Mode of Action.

Yours truly,



Lawrence W. Getlin  
Vice President  
Regulatory/Medical Affairs  
and Quality Systems

2004N-0194

C4